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ATTN.: EVERETT R. WILLIAMS – PATENT APPEALS

FROM: DR. NAZIR A KHAN

RE: NOTIFICATION OF NON-COMPLIANT APPEAL

FAX #: 571-273-8300

DATE: 07/27/2009

PAGES: 9

- ◇ URGENT
- ◇ REPLY ASAP
- ◇ PLEASE RESPOND/COMMENT
- ◇ PLEASE REVIEW
- ◇ FOR YOUR INFORMATION

Comments:

**In the United States Patent and Trademark Office**

**JUL 27 2009**

**In Response To Notification of Non-Compliant Appeal Brief**

**(37 CFR 41.37) Mailed On 07/09/2009**

Appn. Number: 10/812,380  
Filing Date: March 29, 2007  
Applicant(s): Iftikhar Khan, Nazir A. Khan  
Examiner: Leslie R. Deak  
Group Art Unit: 3761  
Title: HYBRID ARTERIOVENOUS SHUNT  
Attorney Docket: 1800-000001

Mail Stop AF

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

The following response is submitted:

**In Response To Non-Compliant Appeal Brief Under (37 CFR 41.37)**

**Status of The Claims** – All claims 1-20 are rejected, and all are appealed.

**Status of Amendments** – Claims 1, 10, 13 and 17 were amended before the final rejection and were not entered by the examiner. Amendments were made in compliance with the specifications, with no new changes or new matter. Amendment of the claims after the final rejection were made in claims 2,3,7,10,18,19 under 37 CFR 41.33 on April 30<sup>th</sup>, 2009. These amendments are in compliance with the specification, with no new matter.

**Summary of Claimed Subject Matter** –

Hybrid arteriovenous shunt of the claimed invention is a subcutaneous conduit connecting an artery to right atrium of the heart so that blood continuously flows to the right atrium of the heart at arterial without any contact of blood with vein wall.

The apparatus comprising means for purification of blood called hemodialysis in chronic renal failure patients. Structurally the apparatus consists of three parts, a graft connected to an artery, a single lumen venous outflow catheter which goes to the right atrium of the heart and a cuff connecting the graft and venous outflow catheter (See abstract of patent application). The cuff is surgically anastomosed to the terminal end of the graft, and the venous outflow catheter fits in the cuff (See abstract of the patent application, pg. 3 specification paragraph [0048] and Figs. 1,2,3 of patent application). The venous outflow catheter is 1mm smaller than the graft (See pg. 3 specification paragraph [0048] of patent application).

The manner of performing hemodialysis consists of taking the blood from the graft to the machine where after purification, the blood is returned back to the graft and then through the venous outflow catheter into the right atrium (See abstract of the patent application, pg. 3 specification paragraphs [0056], [0057], [0058], [0060], pg. 4 specification paragraph [0060] and Fig. A for illustration of hybrid arteriovenous shunt in upper extremity per pg. 3 specification paragraph [0056]).

A recognized complication of arteriovenous graft is development of neointimal hyperplasia from vein wall damage due to high volume flow at high pressure flowing into the vein. The vein reacts with cells of the inner layer of the vein hypertrophy and multiply, leading to neointimal hyperplasia, vein stenosis, and graft failure in 80% of cases (See specification paragraphs [0003], [0006] of patent application and Fig. B for illustration).

In the claimed invention, as the purified blood at high pressure is directly deposited into the right atrium, there is no contact of high pressure high volume blood to the vein wall, the complication of neointimal hyperplasia and 80% graft failure is totally eliminated (See Pg.3 specification paragraphs [0051], [0056], [0058] of patent application).

Fig. A & B are attached to clarify the subject matter in claimed invention, so as to enable one skilled in the art to understand the function of the invention, how to make it and how to use it. The requirements of 35 USC 112, sixth paragraph are satisfied.

**Independent Claim 1 – An arteriovenous shunt comprising:**

- a. an arterial graft comprising a body, a lead end and a terminal end, said lead end being configured for subcutaneous connection to an artery by anastomosis, wherein said arterial graft has a first diameter (See Pg.4 claim1, subsection a of patent application, and drawings 2 and 3).
- b. a single lumen venous outflow catheter comprising an intake end and depositing end, said depositing end being configured for insertion through a vein into the right atrium of the heart, wherein said venous outflow catheter has a second diameter different from said first diameter (See Pg. 4 line 1, subsection b of patent application, specification pg. 3 paragraphs [0048], [0056], [0057] and Fig. 2 and 3).
- c. a cylindrical cuff operable to direct passage of blood from said arterial graft to said venous outflow catheter, said cuff comprising an inlet in blood communication with an outlet:
  - i. said inlet being disposed about and connected to said terminal end of said arterial graft; and (See pg. 4 line 1(c) subsection numerals i and ii of patent application, see abstract disclosure of patent application pg. 3 specification paragraph [0048]).
  - ii. said outlet being disposed about and connected to said intake end of said venous outflow catheter, wherein said cuff provides a secure fit for said arterial graft first diameter and said venous outflow catheter second diameter. (See pg. 4 line 1(c) subsection numerals i and ii of patent application, specification paragraphs [0048], fig.1 of patent application, and abstract disclosure of patent application).

**Independent Claim 13 – A system for performing hemodialysis on a patient comprising:**

- i. an arterial graft comprising a body, a lead end and a terminal end, said lead end being configured for subcutaneous connection to an artery by anastomosis, wherein said arterial graft has a first diameter; and (See pg.4 of patent application, Line 13(a) numeral i of specification of patent application and Fig. 2 and 3 of patent application).
- ii. A single lumen venous outflow catheter comprising an intake end and depositing end, said depositing end being configured for insertion through a vein into the right atrium of the heart, wherein said venous outflow catheter has a second diameter different from said first diameter (See pg. 4 of patent application, line 13a numeral ii of specification and paragraph [0048] on page 3 and Fig. 2 and 3 of patent application).
- iii. A cylindrical cuff operable to direct passage of blood from said arterial graft to said venous outflow catheter, said cuff comprising an inlet with blood communication with an outlet: 1. said inlet being disposed about and connected to said terminal end of said subcutaneous graft; and 2. said outlet being disposed about and connected to said intake end of said venous outflow catheter; wherein said cuff provides a secure fit for said arterial graft first diameter and said venous outflow catheter second diameter (See pg. 4 of

patent application, line 13a numeral iii, subsections 1 & 2 specification pg. 3 paragraph [0048], Fig. 1, 2 and 3, and abstract of patent application).

**Independent Claim 17 –**

17. A method of performing hemodialysis on a patient comprising:

- a. surgically inserting an arteriovenous shunt into a patient (See pg.4, line 17 subsection a), wherein said arteriovenous shunt comprises:
  - i. an arterial graft comprising a body, a lead end and a terminal end, said lead end being configured for subcutaneous connection to an artery by anastomosis, wherein said arterial graft has a first diameter (See pg.4, line 17 subsection a, numeral i of patent application, and fig. 2 and 3 of the patent application).
  - ii. A single lumen venous outflow catheter comprising an intake end and depositing end, said depositing end being configured for insertion through a vein into the right atrium of the heart, wherein said venous outflow catheter has a second diameter different from said first diameter (See line 17 subsection a, numeral ii and Pg.3 specification paragraphs [0048], [0056], [0057], and fig. 2 and 3 of patent application).
  - iii. A cylindrical cuff operable to direct passage of blood from said arterial graft to said venous outflow catheter, said cuff comprising an inlet in blood communication with an outlet:
    1. said inlet being disposed about and connected to said terminal end of said arterial graft; and (See pg.4 line 17(a), numeral iii, subsection 1).
    2. said outlet being disposed about and connected to said intake end of said venous outflow catheter, wherein said cuff provides a secure fit for said arterial graft first diameter and said venous outflow catheter second diameter (See pg.4 line 17(a), numeral iii, subsection 2 and pg.3 specification paragraphs [0048], fig. 1,2 and 3 and abstract disclosure of patent application).
- b. connecting said arterial graft to a hemodialysis apparatus; (Pg. 4 line 17 subsection b)
- c. collecting blood from the patient through said arterial graft; (Pg.4 line 17 subsection c)
- d. passing blood through the hemodialysis apparatus; (Pg.4 line 17 subsection d)
- e. collecting purified blood through the hemodialysis apparatus; and (Pg. 4 line 17 subsection e)
- f. transmitting said purified blood through said cuff into said venous outflow catheter (See pg. 4, line 17 subsection f) which deposits blood directly into the right atrium (See Pg. 3 specification paragraphs [0051], [0056], [0057] [0058], [0060] , Pg. 4 specification paragraph [0060], Fig. 1,2 and 3 and abstract of patent application).

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**Grounds of Rejection To Be Reviewed On Appeal (37 CFR 41.37)**

1. Drawings Fig. 1 objected under 37CFR1.83a on basis of cuff having graded inside diameter as set forth in claims 1,13 and 17.
2. Claims 1-5, 7-10, 12-14, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al.
3. Claims 6, 11, 15, 16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al, further in view of US 5,591,226 to Trerotola et al.
4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,591,226 to Trerotola et al.
5. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al, further in view of US 5,509,897 to Twardowski et al.

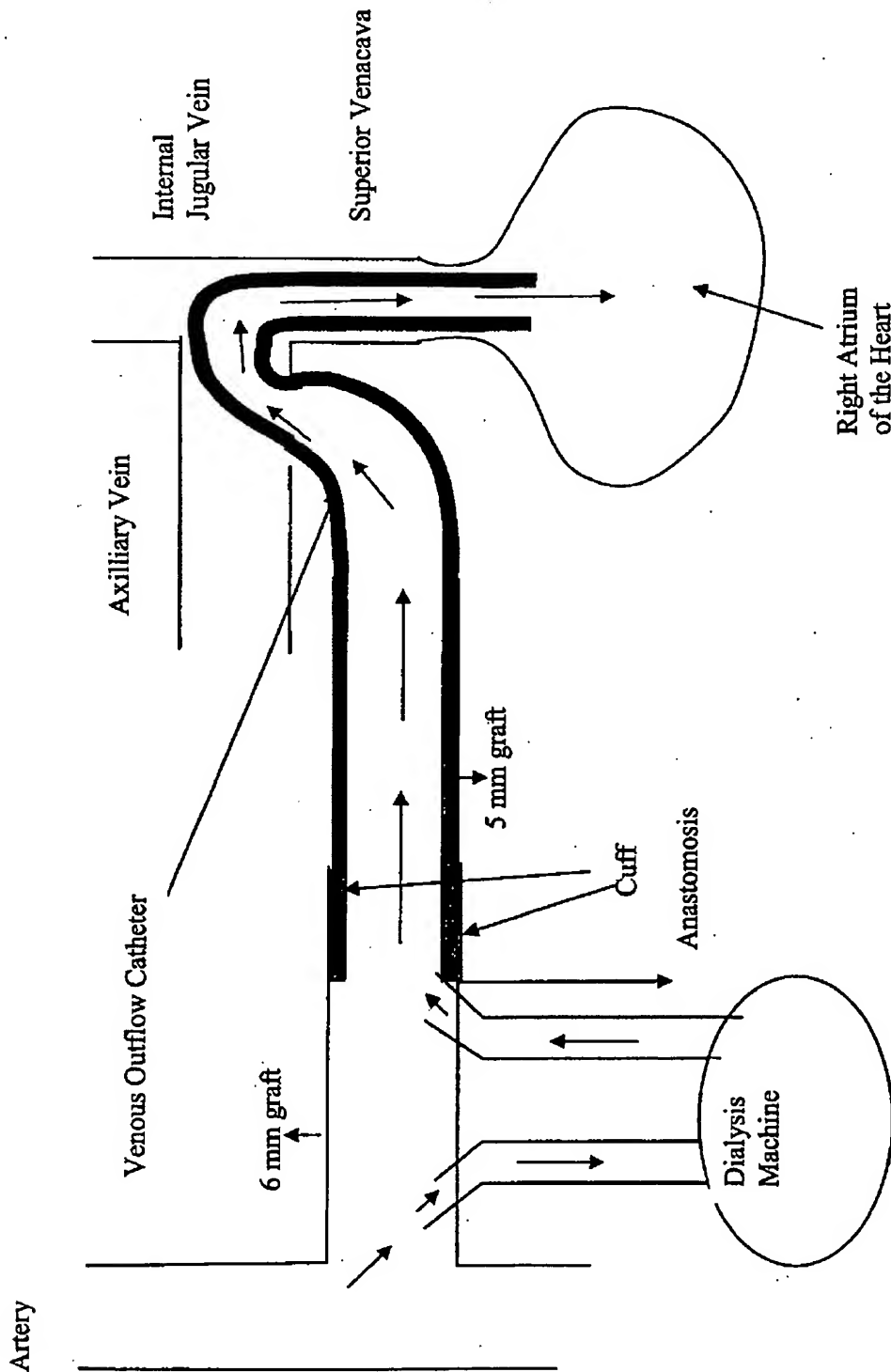
Appellants are not represented by an attorney or a registered agent.

Any questions, please feel free to contact me at 312-329-1100.

Sincerely Yours,

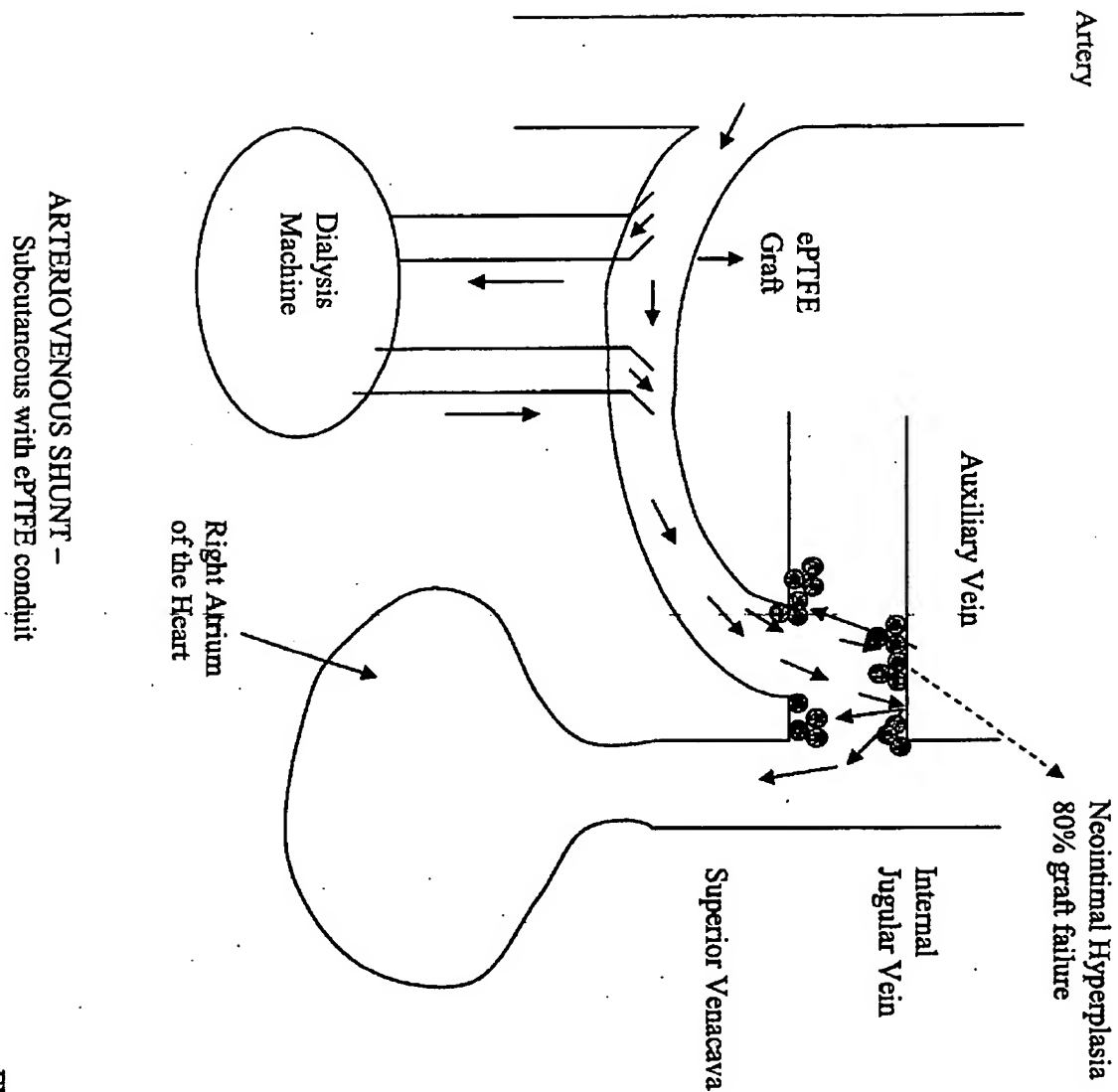
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Hybrid Arteriovenous Shunt  
Upper Extremity

FIG. A



ARTERIOVENOUS SHUNT -  
Subcutaneous with ePTFE conduit

FIG. B





## UNITED STATES PATENT AND TRADEMARK OFFICE

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10/812,380	03/29/2004	Ifikhar Khan	1800-000001	2606
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Please find below and/or attached an Office communication concerning this application or proceeding.